



FOR YOUR INFORMATION

Guidelines and Guideline Harmonization

1. What are Test Guidelines?

Test guidelines are documents that specify the methods that EPA recommends be used to generate data to support the registration of a pesticide or the decision making process for an industrial chemical. The Agency has issued test guidelines for health and environmental effects studies and for the collection of exposure data, as well as for efficacy studies for pesticides. These data are used by the Agency to perform risk assessments and make regulatory decisions.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires prior approval, or registration, of pesticides before they can legally be used in the United States. EPA registers pesticides based on health and environmental effects studies required under regulations contained in Title 40 of the Code of Federal Regulations, Part 158 (40 CFR 158). These regulations specify which tests are required for different types of pesticides by scientific discipline (for example, product chemistry, environmental fate, toxicology, aerial drift evaluation, wildlife and aquatic organisms, etc.). The test guidelines were made available through National Technical Information Service (NTIS). Additional information on standards for conducting acceptable tests and data evaluation and reporting procedures is available in advisory documents developed by the Office of Pesticide Programs (OPP) and collectively referred to as Pesticide Assessment Guidelines.



Chemicals other than pesticides are regulated under the Toxic Substances Control Act (TSCA). Whenever EPA requires data to be submitted under TSCA, the Agency must publish a regulation containing all the test guideline requirements, or referring to a previously issued regulation. The guidelines are published by the Office of Pollution Prevention and Toxics (OPPT) in 40 CFR, Parts 795-799.

2. Why is EPA "harmonizing" its guidelines?

Efforts to update and, where applicable, harmonize OPP and OPPT test guidelines began in the early 1990's. The goal is to produce a common, standardized set of guidelines for studies required under FIFRA and TSCA and to harmonize EPA's requirements with guidelines established by the Organization for Economic Cooperation and Development (OECD), an international organization whose membership includes most industrialized nations which maintain comprehensive testing requirements for pesticides and industrial chemicals. The establishment of a single set of harmonized guidelines will reduce the burden on chemical producers and conserve scientific resources, by reducing

inconsistent and often largely duplicative study requirements imposed by EPA and other OECD members.

In addition to harmonizing with each other and OECD, OPP and OPPT are also updating test guidelines that are unique to each program. This will help ensure that the data supporting EPA's regulatory decisions reflect current scientific standards.

3. Will the harmonized and updated test guidelines be subject to scientific review by experts outside EPA?

Yes, whenever substantive changes are made or new guidelines are issued, they will be submitted for peer review by panels of scientific experts. New or substantially revised guidelines will also be made available for public comment by notice in the Federal Register.

Guidelines which are not changed in any substantive way will not be subject to peer review or public comment, but will simply be republished as part of a unified library, as described below.

4. What Guidelines does EPA plan to issue?

OPPTS will issue its updated and harmonized test guidelines as a unified library, with numerical designations that are different from the designations provided in the Code of Federal Regulations or at NTIS. The library will include the following series of guidelines, by discipline:

- Series 810 - Product Performance Test Guidelines
- Series 830 - Product Properties Test Guidelines
- Series 835 - Fate, Transportation and Transformation Test Guidelines
- Series 840 - Spray Drift Test Guidelines
- Series 850 - Ecological Effects Test Guidelines
- Series 860 - Residue Chemistry Test Guidelines
- Series 870 - Health Effects Test Guidelines
- Series 875A - Occupational and Residential Exposure Test Guidelines
- Series 875B - Post-Application Exposure Test Guidelines
- Series 880 - Biochemical Pesticides Test Guidelines
- Series 885 - Microbial Pesticides Test Guidelines

The schedule for completing review and revision of these guidelines is detailed on the attached chart.

5. How can I obtain copies of the revised guidelines?

Field operations Division (7506C) Office of Pesticide Programs Environmental Protection Agency 401
M St., SW. Washington, DC 20460

In person or for courier pick-up:

Public Docket and Freedom of Information Field Operations Division (7506C)
Office of Pesticide Programs
Environmental Protection Agency
Rm. 1132
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA

Telephone: (703) 305-5805

Electronically:

Guidelines are available electronically in ASCII and PDF format via Internet to by sending an e-mail request to "guidelines@epamail.epa.gov"; or via the EPA Public Access Gopher(gopher.epa.gov) under the heading "Environmental Test Methods and Guidelines."

Final guidelines are available via Internet, as described above, or through the Government Printing Office (GPO).

The requested copies from GPO on-line by modem, dial 202-512-1387, telnet and ftp:fedbbs.access.gpo.gov(IP 162.140.64.19); internet: <http://fedbbs.access.gpo.gov>. To request computer disk or paper copies, call 202-512-1532.

Draft guidelines which have been made available for comment can be obtained by mail, in person or electronically, as follows:

By mail: Public Docket and Freedom of Information Section
Field Operations Division (7506C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, DC 20460

In person or for courier pick-up:

Public Docket and Freedom of Information Section
Field Operations Division (7506C)
Office of Pesticide Programs
Environmental Protection Agency
Rm. 1132
Crystal Mall 2
1921 Jefferson Davis Highway

Arlington, VA
Telephone: (703) 305-5805

Electronically:

Guidelines are available electronically in ASCII and PDF format via Internet to by sending an e-mail request to "guidelines@epamail.epa.gov"; or via the EPA Public Access Gopher(gopher.epa.gov) under the heading "Environmental Test Methods and Guidelines."

6. How can I get copies of existing test guidelines that have not yet been revised and updated?

Guidelines for pesticide studies to be submitted to OPP are available from the National Technical Information Service (NTIS) Fields/306F U.S. Department of Commerce Springfield, VA 22161, Fields/306F

Guidelines for studies of other chemicals to be submitted to OPPT are found in the Code of Federal Regulations, 40 CFR Parts 795-799.

7. How can I obtain more information about the guidelines harmonization project and specific guidelines revisions?

For technical information about specific guidelines, consult the attached chart and schedule. For general information, contact:

TSCA Hotline

TAIS/7408, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460.
Telephone: (202) 554-1404; e-mail: TSCA-Hotline@epamail.epa.gov,

or

Communications Branch

Telephone: (703) 305-5017
Fax: (703) 305-5558

8. What is EPA's schedule for completing its guideline revisions?

OPPTS Test Guidelines Schedule

Series	Guideline Title	Draft Published	Peer Review	Final Published	For Technical Information Contact
810	Product Performance	Winter/Spring 1996/97	Spring 1997		Tobi Colvin-Snyder 305-5540
830	Product Properties	60 FR 44343 Aug. 25, 1995	September 27, 1995	August 1996	Robert Boethling 260-3912 Dick Griffith 305-5826
835	Fate, Transport and Transformation	61 FR 16486 April 15, 1996	May 30, 1996 (OPPT guidelines); Winter 1996/97 (OPP guidelines)	August 1996 (OPPT guidelines); Spring 1997 (OPP guidelines)	Robert Boethling 260-3912 Mah Shamim 305-5025
840	Spray Drift	-----	Not required	Summer 1996	Arnet Jones 305-7416
850	Ecological Effects	61 FR 16486 April 15, 1996	May 29,30, 1996	Winter 1996/97	Robert Morcock 260-1265 Leslie Touart 305-6134
860	Residue Chemistry	60 FR 44343 Aug. 25, 1995	Sept. 27, 1995	August 1996	Randolph Perfetti 305-5381 Richard Loranger 305-6912
870	Health Effects	61 FR 31522 June 20, 1996	October 1996	Winter 1996	William Sette 305-6375 Leonard Keifer 260-1548
875A	Occupational and Residential Exposure: Application Exposure	-----	Not required	61 FR 8279 March 4, 1996	Alan Nielsen 305-5242

Series	Guideline Title	Draft Published	Peer Review	Final Published	For Technical Information Contact
875B	Occupational and Residential Exposure: Post-Application Exposure	-----	Not required	61 FR 8279 March 4, 1996	Alan Nielsen 305-5242
880	Biochemicals	-----	Not required	61 FR 8279 March 4, 1996	William Schneider 308-8683
885	Microbial Pesticides	-----	Not required	61 FR 8279 March 4, 1996	William Schneider 308-8683